



DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2022-0083]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny the applications from three individuals treated with an ICD who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, DOT, 1200 New Jersey Avenue, SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number, FMCSA-2022-0083, in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Background

On April 27, 2022, FMCSA published a *Federal Register* notice (87 FR 25079) announcing receipt of applications from three individuals treated with ICDs and requested comments from the public. The individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on May 27, 2022, and one comment was received.

FMCSA has evaluated the eligibility of the applicants and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(4). A

summary of each applicant's medical history related to their ICD exemption request was discussed in the April 27, 2022, *Federal Register* notice and will not be repeated here.

The Agency's decision regarding this exemption application is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007 evidence report titled "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,"¹ and a December 2014 focused research report titled "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.² The advisory criteria for § 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. ICDs are disqualifying due to risk of syncope.

II. Discussion of Comments

FMCSA received 109 comments in this proceeding. All of the comments were from private citizens. The majority of the comments were in support of Mr. Abiud Ortuno. The remaining comments were not attributed to a specific applicant. All of the comments were supportive of granting ICD exemptions to the applicants. No adverse comments were received in this proceeding. Several commenters felt that FMCSA should rely on the authority of a cardiologist's clearance to receive an ICD exemption to drive a CMV. In one commenter's opinion, CMV operators and other people in general without ICDs suffer cardiac arrest in greater numbers than those with ICDs, and whether younger or older, one cannot predict when this could happen. The commenter believes that texting

¹ The report is available on the internet at <https://rosap.ntl.bts.gov/view/dot/16462>.

² These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. *Cardiovascular: § 391.41(b)(4)*, paragraph 4, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

and other medical conditions were more of a risk to safety while driving a CMV than the possibility of having a cardiac arrest and encouraged FMCSA to grant the exemptions due to the shortage of CMV drivers. Another commenter stated that FMCSA should revise its regulations in accordance with current medical standards and with 49 U.S.C. 31136(e) and 31315. One commenter referred to two research studies, one from the American College of Cardiology that supported statistically low fatality rates from road accidents among individuals with ICDs than fatality rates of the general population, and a second study of a subgroup analysis of the AVID trial, in which the annual incidence of accidents in the ICD population was estimated to be 3.4 percent per year, significantly lower than the 7.1 percent per year accident rate in the general driving population in the USA.”

Regarding the comment concerning medical clearance by a cardiologist to grant ICD exemptions, while FMCSA does not rely solely on a cardiologist’s medical clearance or opinion to determine whether to grant an ICD exemption, FMCSA does consider the cardiologist’s medical documentation and opinions received as a part of the applicant’s exemption request in evaluating whether to grant an exemption. In response to the comments that other safety risks are greater than the risk of ICD deployment due to a cardiac arrest, and that FMCSA should update our standards and revise them in accordance with 49 U.S.C. 31136(e) and 31315, FMCSA is concerned about all safety risks concerning CMVs. FMCSA engages in research, and partners with the Agency’s Medical Review Board, medical experts, and our stakeholders to provide evidence-based rulemaking and guidance with the ultimate goal of keeping our roadways safe. FMCSA’s exemption process is consistent with the current requirements of 49 U.S.C. 31136(e) and 31315 as further discussed in the Basis for Exemption Determination section that follows in the next section. In response to the comment regarding the two research studies, the studies do not appear to have a clear relevance to ICDs and CMV-related crashes. The

commenter did not include specific citations for the study information that was referenced. The Antiarrhythmics Versus Implantable Defibrillators study appears to evaluate the efficacy of cardiac medication treatment over treatment with an ICD rather than ICD crash risk.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of the applicants' medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on individuals with ICDs and CMV driving does not support that individuals with ICDs who operate CMVs are able to meet an equal or greater level of safety.

III. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following applicants have been denied an exemption from the physical qualification standards in § 391.41(b)(4):

Timothy Broome (SC); Bryce A. Norman (CA); Abiud J. Ortuno (FL)

The applicants have, prior to this notice, received a letter of final disposition regarding their exemption request.

The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The names of these individuals published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,
Associate Administrator for Policy.

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